UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VISION BIOSYSTEMS (USA) TRADING INC., Plaintiff, v. VENTANA MEDICAL SYSTEMS, INC., Defendant.	C.A. No. 03-CV-10391-GAO
VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. VISION BIOSYSTEMS INC., Defendant.	C.A. No. 05-CV-10614-GAO

VISION'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR LEAVE TO SERVE THE ATTACHED EXPERT REPORT FROM DR. BALIS ON THE ISSUE OF OBVIOUSNESS

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INTRODUCTION

Vision BioSystems, Inc. ("Vision") respectfully seeks leave of Court to serve a brief expert report from Dr. Ulysses G.J. Balis, M.D., on the issue of obviousness of Ventana's U.S. Patent No. 6,352,861 ("the '861 patent"). The report is attached as Exhibit 1 ("Balis Report").

One week ago today, the United States Supreme Court, in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. __ (2007) (Ex. A),[1] issued what is being called "the court's furthest-reaching ruling in the field [of patent law] for decades." *Rulings Weaken Patents' Power*, Washington Post, May 1, 2007, at D01 (Ex. B). Because of *KSR*'s dramatic changes to the obviousness standard and the evidence pertinent to it, Vision and Ventana conferred after the *KSR* decision in an attempt to reach agreement on supplementing expert reports on obviousness. Incredibly, while Ventana is taking the position that it is entitled to provide supplemental expert testimony under *KSR* both from an engineering expert and a pathologist expert, Ventana refuses to afford Vision the same opportunity, objecting to Vision providing a report from a pathologist expert. Accordingly, Vision brings this motion, with the attached proposed report from Dr. Balis (Ex. 1).

The Balis Report is necessitated by the new "market" inquiry test of *KSR*. In *KSR*, the Supreme Court held that the Federal Circuit's obviousness standard was too "rigid" and articulated a new obviousness test that takes into account not just prior art documents but also requires consideration of the demands and needs of customers for the patented technology, which in this case are pathologists. Under *KSR*, a patent that claims a combination of known elements is obvious if a person of ordinary skill in the art, facing those market demands, would have recognized a benefit to combining prior art in the way that the patent claims.

[1] Exhibits identified by the letters A through Y, designated herein as "Ex. __," refer to exhibits identified and attached to the First Declaration and Second Declaration (under seal) of Douglas E. Ringel filed concurrently herewith.

The attached Balis Report addresses the three key inquiries under *KSR*'s "market" test – (1) identifying the market demands of the customers (pathologists), (2) identifying whether those market demands presented a problem for which there was a known solution, and (3) providing an opinion as to whether it would have been obvious to persons of ordinary skill in the art to address those market demands by combining known solutions. Because *KSR* requires these "market" inquiries, the Balis Report is not only substantially justified but also will be helpful to the Court in addressing the appropriate obviousness factors under the new Supreme Court law.

The Balis Report does not prejudice Ventana. During upcoming expert discovery, Vision will be submitting an expert report from Dr. Balis on non-infringement, an issue that Ventana concedes Dr. Balis is entitled to address. Accordingly, Ventana will be taking a deposition of Dr. Balis in any event. Vision is providing the attached Balis Report on obviousness well in advance of that upcoming expert discovery and over six months before trial, so there is plenty of time for Ventana to address it. Ventana has a pathologist expert, Dr. Hicks, who has already addressed the prior art and obviousness issues (albeit under the old standard), so Ventana cannot claim that it is not in a position to respond. In fact, Ventana itself seeks to provide a supplemental report from Dr. Hicks under *KSR*.

The attached Balis Report has one paragraph (¶ 22) addressing "secondary factors" that *KSR* confirms must be considered in an obviousness analysis when they are raised by the patentee, factors such as whether the invention achieved "commercial success" due to the claimed features and whether the invention satisfied a "long-felt need." Because applying the *KSR* "market" inquiry requires consideration of these "secondary factors," Dr. Balis has addressed them. Moreover, since the parties last went through fact discovery over two years ago,

further facts have transpired and additional documents have been produced that are highly relevant to these "secondary factors," further justifying the report from Dr. Balis.

Finally, the attached Balis Report has one paragraph (¶ 23) that addresses one prior art patent that was not previously addressed in the case, U.S. Patent No. 5,122,342 to McCulloch. The McCulloch patent is being asserted as prior art against the '861 patent in a different litigation between Ventana and Biogenex. The McCulloch patent is highly pertinent to invalidity. Allowing Vision to address McCulloch now will not cause any prejudice to Ventana, since Ventana and both of its experts have already addressed McCulloch in *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, No. 03-92 (D. Ariz.) ("the *Biogenex* case").

PROCEDURAL POSTURE AND BACKGROUND

This case is actually two civil actions consolidated for trial, both involving Ventana's assertion of the '861 patent against Vision. In the first action, Civil Action No. 03-CV-10391-GAO ("the 2003 action"), Ventana asserted that Vision's now-discontinued "Bond—Bar Code" instruments infringed the '861 patent. In 2004, the Court ruled on summary judgment that Vision's "Bond—Bar Code" instruments infringed. (D.I. 103, p 17).[2] In the second action, Civil Action No. 05-CV-10614-GAO ("the 2005 action"), Ventana asserts that Vision's "Bond—OCR" instruments infringe the '861 patent. Vision denies infringement and asserts that the '861 patent is invalid for obviousness. The parties have agreed to a bench trial. (D.I. 126, pp. 5-6).

The parties' original joint discovery plan in the 2003 action provided that the parties' opening expert reports would address issues on which they had the burden of proof. (D.I. 19, p. 2). Vision served an opening expert report on obviousness from a mechanical engineer, Mr. Doug Koebler, on April 8, 2004. (Ex. C). In response, Ventana served an expert report from a

[2] All D.I. numbers refer to the 2003 action, unless otherwise noted.

mechanical engineer, Dr. Andre Sharon (Ex. D), as well as an expert report from a pathologist, Dr. David Hicks. (Ex. E). Although Ventana bears the burden of proving a prima facie case of the so-called "secondary factors" of non-obviousness under *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which include the factors of whether there was a "long-felt need" for the invention or whether the invention has achieved "commercial success," neither Dr. Sharon nor Dr. Hicks raised either long-felt need or commercial success at that time.

On January 10, 2005, Vision served a supplemental interrogatory response on obviousness listing six newly discovered prior art references. At a hearing two days later, the Court granted Vision leave to file a supplemental expert report addressing these new references (D.I. 107, p. 16), which Vision did in a supplemental expert report from Dr. Koebler. (Ex. F). In response, in March 2005, Ventana again submitted reports from Dr. Sharon and Dr. Hicks. This time, however, Dr. Hicks for the first time asserted that a "long-felt need" existed for Ventana's claimed invention and that Ventana's instruments have achieved "commercial success" due to the invention, thus allegedly providing "secondary factor" evidence that the claimed invention was not obvious. (Ex. G, ¶¶ 9-10).

The 2003 action was originally set for trial of the obviousness issue in July 2005. When the July 2005 trial was postponed because of a scheduling conflict, the parties then agreed to have the liability issues from the 2003 action tried together with the liability issues from the then-new 2005 action, in a joint trial that the Court scheduled for November 2005. (D.I. 126). In view of the discovery that needed to take place in the 2005 action and the relatively short time left to the November 2005 trial, Vision at that time agreed to keep the obviousness record closed. (D.I. 16 in the 2005 action; Ex. H (E. Leff letter 9/12/05)). The circumstances since then, however, have changed substantially.

On October 6, 2005, the U.S. District Court for the District of Arizona entered a final, appealable judgment of non-infringement in the *Biogenex* case. The *Biogenex* case involves the same '861 patent asserted in this case. In view of the *Biogenex* ruling, Ventana and Vision jointly requested that the Court vacate the November 2005 trial date and stay the case while Ventana appealed the *Biogenex* decision. (D.I. 136; D.I. 47 in the 2005 action; D.I. 151).

The lengthy appeal process extended from 2005 into 2007. In February 2007, the Federal Circuit issued its mandate vacating the *Biogenex* decision.

After the *Biogenex* appellate ruling, this case has now become active again. The parties have been attempting to work out the scope of upcoming supplemental discovery in view of a trial now scheduled for November 13, 2007. The parties have agreed to supplement fact discovery (document productions and written discovery responses) on the issues of: (1) whether Vision's accused "Bond—OCR" device infringes the '861 patent, and (2) "commercial success," which is relevant to the issue of obviousness of the '861 patent. (Ex. I (D. Ringel letter 4/12/07); Ex. J (D. Ringel letter 4/16/07); Ex. K (N. Stafford letter 4/13/07 ("Ventana agrees to provide supplemental fact discovery responses and production on the narrow issues of licensing and commercial success."). The parties also have agreed to a schedule for expert discovery to occur after this fact discovery, with opening expert reports due June 14, 2007, responsive expert reports due July 12, 2007, and expert depositions to be completed by August 1, 2007. The parties disagree, however, on the scope of expert discovery. Both sides agree that expert discovery will address the issue of infringement. Both sides also agree that last week's Supreme Court decision in *KSR*, which dramatically altered the obviousness inquiry, requires supplemental expert reports on obviousness. Ventana, however, is taking the untenable position that only Ventana should be allowed to present supplemental expert *pathologist* testimony under

KSR, because Ventana previously submitted an obviousness expert report from its pathologist Dr. Hicks and Vision did not previously submit an obviousness expert report from its pathologist, Dr. Balis. (Ex. L (D. Ringel letter 5/3/07); Ex. M (N. Stafford letter 5/1/07)).

In order to avoid any claim of prejudice from Ventana, Vision is submitting the Balis Report at this early date, well in advance of upcoming expert discovery and long before trial. Vision will be submitting an expert report from Dr. Balis on non-infringement at the time rebuttal reports are due on July 12, 2007, and Ventana will thereafter be taking a deposition of Dr. Balis.

ARGUMENT

I. The Law Favors Resolution of Cases on Their Merits and Permits Supplemental Expert Reports When "Substantially Justified or Harmless."

"[T]he intent of the disclosure rules [is] 'to facilitate a fair contest with the basic issues and facts disclosed to the fullest practical extent.'" *Diomed, Inc. v. Angiodynamics, Inc.*, 450 F.Supp.2d 130, 136 (D. Mass. 2006), *quoting Poulis-Minott v. Smith*, 388 F.3d 354, 358 (1st Cir. 2004). While disclosure deadlines serve the important purpose of enabling the efficient administration of a case, the preclusion of relevant evidence, while at times necessary, is a "grave step" that runs counter to the goal of the truth-finding process. *Jackson v. Harvard University*, 900 F.2d 464, 469 (1st Cir. 1990); *see also Foman v. Davis,* 371 U.S. 178, 181-82 (1962) (the law favors deciding cases on their merits rather than on technicalities).

The Supreme Court has held that there is a "strong public interest" in the correct resolution of questions of patent validity, as invalid patents can stifle legitimate competition. *Cardinal Chem. Co. v. Morton Int'l, Inc.,* 508 U.S. 83, 100 (1993); *see also Smithkline Beecham Corp. v. Apotex Corp.,* 403 F.3d 1331, 1354 (Fed. Cir., 2005) (Gajarsa, J., concurring) (It is "important to the public that competition should not be repressed by worthless patents.")

(internal citations omitted). Accordingly, the Supreme Court has stated that the public interest favors a district court "'inquiring fully into the validity of [a] patent.'" *Cardinal Chem.*, 508 U.S. at 100, *quoting Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945). In cases where an invalid patent is used to stifle competition in areas of critical technology—as with the cancer detection instruments in this case—the best way to protect the public interest is "to allow the validity of a patent, which was originally obtained in ex parte proceedings in the PTO, [to] be challenged in court." *Smithkline*, 403 F.3d at 1355 (internal citations omitted).

Leave to serve a supplemental expert report should be granted where the report is "substantially justified or harmless." *Diomed*, 450 F.Supp.2d at 136, *quoting Poulis-Minott,* 388 F.3d at 358; *see also* Fed. R. Civ. P. 37(c)(1). A supplemental report can be "substantially justified" by developments that occur after the initial expert report deadlines. *See Diomed*, 450 F.Supp.2d at 137 (customer information obtained after initial deadlines). Even if no substantial justification exists, courts permit belated expert evidence if the delay was "harmless." *Id.* at 136. Overall, in determining whether to allow a supplemental expert report, a court should concentrate on such factors as the "history of the litigation, the proponent's need for the challenged evidence, the justification (if any) for the late disclosure, and the opponent's ability to overcome its adverse effects," such as whether there is any unfair "surprise" or "prejudice." *Id.* at 136-37, *quoting Macaulay v. Anas*, 321 F.3d 45, 51 (1st Cir. 2003). With respect to prejudice, a court should look to whether the supplemental report "deprive[s] a [party] of the opportunity to 'depose the proposed expert, challenge his credentials, solicit expert opinions of [its] own, or conduct expert-related discovery.'" *Poulis-Minott,* 388 F.3d at 358, *quoting Lohnes v. Level 3 Communs., Inc.*, 272 F.3d 49, 60 (1st Cir. 2001).

II. The Balis Report Is Substantially Justified and Causes No Prejudice.

A. Last Week's Landmark Supreme Court Decision in *KSR* Substantially Justifies the Balis Report.

Last week's ruling by the Supreme Court in *KSR* changed the standard for determining obviousness and the evidence that a court must consider in determining obviousness. In *KSR*, the Supreme Court addressed the Federal Circuit's "teaching, suggestion, or motivation" test (TSM test), "under which a patent claim is only proved obvious if 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *KSR*, 550 U.S. at __ (*quoting Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323-24 (Fed. Cir. 1999)); (Ex. A, p. 2). In its ruling, the Supreme Court "reject[ed] the rigid approach of the Court of Appeals" and held that obviousness must be determined under "an expansive and flexible approach." (Ex. A, p.11). While the TSM test can provide "helpful insight," the Supreme Court held that the Federal Circuit's "rigid" use of the TSM test constituted error. *Id.* at 15. Instead, the Supreme Court ruled, the obviousness inquiry must consider additional factors, most notably the "market demand" within a particular technology and what a person of ordinary skill would have found obvious in view of that "market demand." *Id.* at 15. The Supreme Court said:

> Helpful insights [like the TSM test] need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. . . . In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that *market demand*, rather than scientific literature, will drive design trends.

Id. at 15 (emphasis added).

The Supreme Court repeatedly stressed the importance of this "market" inquiry. Early in the decision, it said:

> When a work is available in one field of endeavor, design incentives and other *market forces* can prompt variations of it, either in the same field or a different one.

Id. at 13 (emphasis added).

Later, the Supreme Court said:

> Often it will be necessary for a court to look to … the effects of *demands* known to the design community or present in the *marketplace*.

Id. at 14 (emphasis added).

Still later, the Supreme Court said:

> When there is a design *need* or *market pressure* to solve a problem, … a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.

Id. at 17 (emphasis added).

The message from the Supreme Court is clear. One commentator, a partner in the law firm representing Ventana in this case, said the following:

> The [Supreme Court's] replacement test [for obviousness] can be summarized as a "marketplace" test – Justice Kennedy's well-written opinion uses phrases such as "marketplace," "market forces," "market demand," and "market pressure" no less than five times in describing replacement formulations and in holding claim 4 of the Teleflex patent obvious as a matter of law.

Ex. N, p. 2 (*Some Thoughts About KSR v. Teleflex: The "Marketplace" Test for Obviousness*, Michael Barclay of Wilson Sonsini Goodrich & Rosati, April 30, 2007).

The Supreme Court's test has three fundamental inquiries. First, one considers the market needs and demands. Then, one considers whether those market needs and demands posed "a known problem for which there was an obvious solution encompassed by the patent's

claims." *KSR*, 550 U.S. at __; (Ex. A, p. 16). With this background, the "proper question" then to address is "whether a [person] of ordinary skill, facing the wide range of [market] needs created by developments in the field of endeavor, would have seen a benefit" to combining features from the prior art. *Id.* at 20.

Dr. Balis, in the attached report, addresses these three "market" inquiries with respect to this case, i.e., (1) "What market demands existed with respect to the assays described in U.S. Patent No. 6,352,861 ("the '861 patent") at the time of the invention claimed in that patent?", (2) "Did those market demands give rise to a known problem for which there was a known solution in the prior art?", and (3) "Taking into account any such known solution(s), would the subject matter of the claims have been obvious to a person of ordinary skill in the art?" (Ex. 1, ¶¶ 4-22).

The testimony from Dr. Balis will assist the Court in addressing the factors required by the Supreme Court. Because *KSR* requires these "market" inquiries, the Balis Report is "substantially justified." *Diomed*, 450 F.Supp.2d at 136.

B. The *KSR* Case as Well as Recent Discovery Relating to Commercial Success Provide Substantial Justification for Dr. Balis to Address "Secondary Factors" Relating to Obviousness.

A patentee may attempt to rebut an obviousness argument by introducing certain "secondary factors" (also called "objective considerations") relating to non-obviousness. For example, a patentee may introduce evidence to show that there was a "long-felt need" for the solutions provided by the invention. If such a "long-felt need" indeed existed, the fact that nobody made the invention prior to the inventor is evidence tending to show that the invention was not obvious. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1574-75 (Fed. Cir. 1992). Similarly, a patentee may introduce evidence to show that products using the claimed invention have achieved "commercial success." Evidence of "commercial success" due to the invention can be evidence that the invention was not obvious,

the argument being that if the invention was obvious, others would have made the invention in view of the money to be made from it. *See Merck & Co. v. Teva Pharmaceuticals USA*, 395 F.3d 1364, 1376-1377 (Fed. Cir. 2005). In order for this theory to be sustainable, however, the alleged "commercial success" of the product allegedly embodying the patented invention must be due to the features set forth in the claims of the patent, not some other factor. That is, there must be a "nexus" between the commercial success and the claimed invention. *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.,* 106 F.3d 1563, 1571 (Fed. Cir., 1997) (citation omitted).

The patentee—in this case Ventana—bears the burden of proof to establish long-felt need, commercial success, and the required nexus between the alleged commercial success and the claimed invention. *See Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.,* 851 F.2d 1387, 1393 (Fed. Cir. 1988). If the patentee meets this burden, the burden then shifts to challenger to present evidence that the commercial success was due to other factors. *Id.*

Ventana's experts did not raise "long-felt need" or "commercial success" until the very last round of expert reports, when Ventana served the second expert report from Dr. Hicks, on March 11, 2005. (Ex. G, ¶¶ 9-10). This effectively prevented Vision from having an opportunity to respond previously in a responsive expert report.

The parties have agreed to supplement fact discovery relating to commercial success. (Ex. K). Indeed, since 2005, Vision has had significant commercial success selling its "Bond—OCR" instruments, which do not use bar codes on the specimen slides as claimed in the '861 patent. This new evidence is highly pertinent as it flatly contradicts Ventana's claim that commercial success of slide staining instruments is due to the bar coding of slides as claimed in the '861 patent. This recent evidence shows that the commercial success of such instruments is in fact due to factors other than slide bar coding. In addition, just last week Ventana itself

produced additional documents highly pertinent to commercial success. (Ex. O (P. Skinner letter 4/30/07); Ex. T (VEN1036967-1036982); Ex. 1 (Balis Report, ¶ 22, citing recently produced pages VEN 1036972 and VEN 1036968)).

In order to properly address obviousness under *KSR*, one must consider "secondary factors" where raised. *KSR*, 550 U.S. at __; (Ex. A, p. 2). Thus, in addressing the new *KSR* inquiry, Dr. Balis has considered the "secondary factors" that Dr. Hicks raised in his second rebuttal report. (Ex. 1, ¶ 22). In doing so, Dr. Balis has addressed the new fact discovery provided within the last two weeks by both Vision and Ventana. (Ex. 1 (Balis Report, ¶ 22, citing VEN 1036972, VEN 1036968, and VBS-OCR 0167955)). Ventana's agreement to this additional fact discovery is flatly inconsistent with its refusal to allow Vision to address it. It simply makes no sense to provide updated facts yet deny supplemental expert reports to address them. Because addressing *KSR* requires addressing "secondary factors" (where raised), because the new evidence did not exist at the time of the previous expert reports, and because Vision has not previously had the opportunity to respond to Dr. Hicks on "secondary factors," the expert testimony from Dr. Balis is "substantially justified." *Diomed*, 450 F.Supp.2d at 136.

Ventana argues that Vision should not be allowed to address "secondary factors" or add an additional witness on invalidity issues because Vision "agreed" not to do so in a letter in September 2005 in preparation for the scheduled November 2005 trial. (Ex. H (E. Leff letter 9/12/05)). The agreement in that letter, however, was plainly made in context and in view of the law and facts at the time—i.e., before the lengthy stay, before the change in the law of obviousness, before the parties agreed to supplement fact discovery on commercial success in view of the two year hiatus, and before both parties had produced additional documents pertinent to commercial success, which they did in the last two weeks. Vision never agreed to "freeze" the

obviousness record if circumstances changed substantially, which they have. Indeed, Ventana itself agrees that *KSR* requires supplementation on obviousness.

C. Permitting the Balis Testimony Will Not Cause Any Unfair Prejudice to Ventana.

Ventana's proposal that only its expert pathologist may provide testimony under *KSR* is not only unreasonable but is contrary to the truth-seeking goal of the adversarial process. With testimony from Dr. Balis under *KSR*, the Court will have evidence and opinions relevant to the *KSR* inquiries from pathologists on both sides, rather than just from Ventana. The Balis testimony allows the important issue of patent validity to be decided fully and fairly.

Moreover, the Balis testimony will not upset the ultimate goal of the disclosure rules, i.e., "to facilitate a fair contest with the basic issues and facts disclosed to the fullest practical extent." *Diomed*, 450 F.Supp.2d at 136. Vision is providing the Balis Report to Ventana with plenty of time for Ventana to challenge it. Weighing Vision's "need for the challenged evidence" against any unfair "surprise" or "prejudice" (*Id.* at 136-37), the balance tilts strongly in favor of allowing the Balis Report.

In fact, Ventana has no legitimate claim of prejudice. The Balis Report is brief and requires no additional fact discovery other than the additional fact discovery on commercial success to which the parties have already agreed. Dr. Balis will be submitting an expert report on infringement issues, so Ventana will be taking a deposition of Dr. Balis in any event. No additional depositions are required.

Ventana cannot credibly argue that it cannot adequately respond to Dr. Balis's Report. In fact, the far majority of documents cited in the Balis Report were previously and expressly considered by Dr. Hicks in his two reports. (*See* Ex. 1, Balis Report, Tab B). There is ample

time for Ventana and its experts to review the Balis Report and its cited materials and prepare any necessary response.[3]

D. The McCulloch Patent Is Not New to Ventana, and Substantial Justification Exists for Its Inclusion.

The only prior art reference relied upon by Dr. Balis that was not previously considered by Dr. Hicks is U.S. Patent No. 5,122,342 to McCulloch (Ex. P). The Balis Report has one paragraph (¶ 23) addressing McCulloch.

The McCulloch patent is highly pertinent to this case. Like the '861 patent, it discloses an automated apparatus for carrying out immuno-assay tests. The McCulloch patent describes the use of bar codes on microtitre plate carriers with the bar codes identifying the sequence of reagents to be applied to the microtitre plates. The only difference between the McCulloch patent and the '861 patent claims is that McCulloch uses microtitre plate carriers instead of slides. (Ex. 1, Balis Report, ¶ 23). Given the significance of the McCulloch patent, and the "strong public interest" in a district court "inquiring fully into the validity of [a] patent" (*Cardinal Chem.*, 508 U.S. at 100), substantial justification exists for allowing expert testimony regarding the McCulloch patent.

Ventana cannot legitimately claim that it is unfairly prejudiced by allowing testimony on the McCulloch patent. Ventana has already gone through expert discovery as well as summary

[3] Prior to *KSR*, Vision sought Ventana's agreement to having Dr. Balis address obviousness in view of the Federal Circuit's decisions in *Alza Corp. v. Mylan Labs.*, Inc., 464 F.3d 1286 (Fed. Cir. 2006), *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006), and *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006), in response to the prior reports from Dr. Hicks. (Ex. J (D. Ringel letter 4/16/07)). Once *KSR* was decided, in conversations on April 30th and May 1st and in a follow-up letter on May 3rd, Vision sought Ventana's agreement to having Dr. Balis address obviousness under *KSR* (a new standard not addressed by Dr. Hicks), but Ventana would not agree. (Ex. L (D. Ringel letter 5/3/07)). Should the Court grant Vision leave to serve the Balis Report, Vision does not object to Ventana serving a responsive report from Dr. Hicks under *KSR*.

judgment briefing on the McCulloch patent in the *Biogenex* case. Both of Ventana's experts in this case, Dr. Sharon and Dr. Hicks, addressed the McCulloch patent in the *Biogenex* case. (Ex. U (VEN1035325-54) at VEN1035331 and VEN1035340-42; Ex. V (VEN1035264-306) at VEN1035275 ¶ 24 (Dr. Hicks rejecting obviousness in view of prior art cited in Mr. Palmer's report, which included the McCulloch patent as the primary reference); Ex. W (VEN1021083-135) at VEN1021095, VEN1021107 and VEN1021115-20 (Palmer report citing McCulloch to which Dr. Hicks was responding)). In opposing Biogenex's motion for summary judgment of obviousness of the '861 patent based, in part, on the McCulloch patent (which motion was never decided), Ventana fully briefed the issue. (Ex. X (VEN1034665-90) at VEN1034676-77 and VEN1034689).

Ventana did not produce any of the *Biogenex* case materials regarding McCulloch until *after* Vision had already submitted its first expert report from Mr. Koebler and *after* Vision identified on January 10, 2005, the newly-discovered subject matter of Mr. Koebler's second report—which Vision sought leave from the Court to submit. (D.I. 107).[4] Ventana thus effectively prevented Vision from previously raising McCulloch without seeking further leave of Court.

Moreover, Dr. Balis will be addressing the McCulloch patent in any event, when he later submits a report on non-infringement. This is because Ventana asserts that Vision infringes the

[4] Vision received materials relating to McCulloch on January 11 & 15, 2005, *after* Vision identified six additional prior art references in its January 10, 2005 supplemental discovery responses, which Vision sought and obtained leave of Court on January 12, 2005, to address in Mr. Koebler's second supplemental report. (Ex. Q (S. Zimmerman letter 1/14/05, producing Palmer's report, attached as Ex. W); Ex. R (J. Day letter 1/10/05, producing Winkleman's report, attached as Ex. Y); D.I. 107). Ventana later produced significant additional materials relating to McCulloch on September 21, 2005, *after* all obviousness expert reports and depositions in this case had taken place. (Ex. S (S. Zimmerman letter 9/21/05, producing summary judgment briefing and Ventana's expert discovery rebutting Palmer's report, attached as Exs. U, V and X)).

'861 patent under the "doctrine of equivalents," a doctrine under which a patentee attempts to assert a patent scope broader that the literal words of the patent claims. Under controlling law, "an invention representing only a modest advance over the prior art is given a more restricted (narrower range) application of the doctrine" of equivalents. *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1580 (Fed. Cir. 1983); *see also Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 (Fed. Cir. 1993) (where a claimed invention is at most only "a modest advance" over the prior art, it is not entitled to a broad range of equivalents). Accordingly, in his non-infringement report, to which Ventana has no grounds to object, Dr. Balis will be comparing the '861 patent to the McCulloch patent (as well as all of the other prior art) in any event. Ventana will also have the opportunity to depose Dr. Balis on that comparison.

The balance of appropriate factors overwhelmingly favors allowing the evidence. The "need for the challenged evidence" is great, given the significance of McCulloch and the public interest; Ventana's "ability to overcome its adverse effects" is clear, given that it has already fully addressed McCulloch; and there is no unfair "surprise" or "prejudice" to Ventana, given that Vision is providing the Balis Report to Ventana long in advance of upcoming expert discovery and trial. *Macaulay*, 321 F.3d at 51. Because the Balis Report does not "deprive [Ventana] of the opportunity to 'depose the proposed expert, challenge his credentials, solicit expert opinions of [its] own, or conduct expert-related discovery,'" the goals of the disclosure rules are met. *Poulis-Minott,* 388 F.3d at 358, *quoting Lohnes*, 272 F.3d at 60.

CONCLUSION

For the reasons set forth above, Vision respectfully requests that the Court grant its motion for leave to serve the attached expert report from Dr. Balis.

Respectfully submitted,

Dated: May 7, 2007

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EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VISION BIOSYSTEMS (USA) TRADING INC., Plaintiff, v. VENTANA MEDICAL SYSTEMS, INC., Defendant.	C.A. No. 03-CV-10391-GAO
VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. VISION BIOSYSTEMS, INC., Defendant.	C.A. No. 05-CV-10614-GAO

EXPERT REPORT OF ULYSSES G.J. BALIS, M.D.

I. Background and Qualifications

1. I am currently Director of Clinical Informatics and Division Co-Director of Pathology Informatics in the Department of Pathology at the University of Michigan, where I also serve as Associate Professor. Previously, I was Director of Pathology Informatics at Massachusetts General Hospital (MGH), Chief of Pathology and Laboratory Services at Shriners Hospital for Children, Boston Burns Unit, and Assistant Professor of Pathology and Computer Engineering at Harvard Medical School.

2. I hold Bachelor of Science degrees in computer engineering and biology from Duke University and an MD degree from the University of South Florida. I conducted my internship and residency in anatomic and clinical pathology at the University of Utah. Subsequently, I was a Postdoctoral Research Fellow in the Whitaker Foundation B.E.R.E. Program at MGH and the Harvard University Health Sciences and Technology Program, with continued research in tissue engineering at Harvard's Center for Engineering in Medicine at MGH.

3. I am a recipient of several awards and a member of several professional organizations, as listed in my *curriculum vitae*, attached at Tab A. I am a founding member of the Association of Pathology Informatics and currently serve as that organization's President. I have experience in bioinstrumentation design, for example in the areas polymerase chain reaction and synthetic aperture microscopy. My *curriculum vitae* gives further details of my qualifications.

II. Obviousness Analysis of Claims 1-3, 5, 6 and 8 of U.S. Patent No. 6,352,861.

4. I have been asked by Vision BioSystems, Inc. ("Vision") to provide my opinions in response to the following questions:

> (A) What market demands existed with respect to the assays described in U.S. Patent No. 6,352,861 ("the '861 patent") at the time of the invention claimed in that patent?
>
> (B) Did those market demands give rise to a known problem for which there was a known solution in the prior art?
>
> (C) Taking into account any such known solution(s), would the subject matter of the claims have been obvious to a person of ordinary skill in the art?

5. In answering the above questions, I have considered the materials identified in Tab B. I have also considered: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) objective considerations,

such as whether the invention achieved "commercial success" due to the claimed features or met a "long-felt need."

6. The scope and content of the prior art includes the prior art cited or discussed in the '861 patent and the prior art discussed in the two reports of Vision's engineering expert, Mr. Koebler, as listed in Tab B. I have also considered U.S. Patent No. 5,122,432 to McCulloch, discussed below.

7. I agree with the definition of the level of ordinary skill in the art previously set forth by Mr. Koebler, identifying a person of ordinary skill as having "a bachelor's degree or equivalent in mechanical engineering, electrical engineering, or computer science," "significant experience in the design of instruments which automate the preparation of samples for diagnosis," and "at least a general understanding of bar code technology and its use in automated systems that process specimens for diagnosis." (Koebler 1, ¶ 17). Mr. Koebler has explained that such a person would consult the intended customer for the instrument being designed. (Koebler 7/2/04 Dep., pp. 223-4). Ventana's engineering expert Dr. Sharon agrees that "developing successful automation requires consultation with the intended customer or end user, which in the case of the '861 patent would be a pathologist." (First Sharon Report, ¶ 7). I agree with this statement.

A. What market demands existed with respect to the assays described in U.S. Patent No. 6,352,861 ("the '861 patent") at the time of the invention claimed in that patent?

8. The '861 patent says the invention "can be used for a wide variety of assays, for example, automatic immunostaining of tissue sections, in situ DNA analysis, imunoassays such as ELISA, and the like." (col. 1, lines 15-19). The claims at issue (claims 1-3, 5, 6 and 8) recite "A method of dispensing reagents onto a slide … ." Assays that involve dispensing reagents onto slides include immunostaining of tissue and cell preparations. (*See, e.g.*, Stark, p. 90).

9. The market demand for these types of immunostaining assays began, to any degree of significance, only in the second half of 1980's. It was in 1985 that the AMA created CPT code 88342 for immunocytochemistry (including tissue immunoperoxidase) (CPT 1985 Codebook, p. 342), which made immunostaining of tissue a billable clinical procedure. In the time period before March 1989 (i.e., at least one year before the March 1990 filing date listed on the '861 patent), the numbers of immunostaining procedures had increased significantly (but were still relatively small by today's standards). (*See* Stark, Brigati). Later events show that the procedures were still developing. In December 1989, a leading publication carried an article reporting efforts that were being made to develop quality control procedures for immunostaining. (Elias). In 1993, the Council of the Association of Directors of Anatomic and Surgical Pathology issued recommendations for reporting immunostaining results. (Banks).

10. Despite the continuing development, it was recognized in the art before March 1989 that the increase in the number of these procedures being performed created a market for automated instruments to perform the procedures. (Stark, Brigati). Indeed, in the 1987-1989 time period, a few instruments for automating immunostaining procedures were developed, for "cost savings, uniformity of slide preparation, and reduction of procedural human errors." ('861 patent, 1:53-2:29; *see also* Stark, Cosgrove/Bowman). The primary issue recognized at the time was how to precisely control the dispensing and processing steps to yield useful results and not waste expensive antibodies. (*See, e.g.*, Stross, p. 106; Stark, p. 92; Cosgrove, p. 23; Brigati, p. 165).

11. In the time period before March 1989, not only had the number of immunostaining procedures being performed increased significantly, but the number of different reagents used and the number of different immunostaining procedures being performed had also increased significantly (but again were still relatively small by today's standards). This created a market

demand for an automated immunostaining instrument that could handle a number of different reagents and perform a number of different procedures.

B. Did those market demands give rise to a known problem for which there was a known solution in the prior art?

12. The market demand for such automated immunostaining instruments presented a known problem – the problem of handling a number of different reagents and performing different procedures on different samples in an efficient and error-free manner. This known problem had a known solution.

13. The Liston '159 patent and the Driscoll reference (collectively "Liston/Driscoll") describe the Paramax system, a clinical chemistry analyzer able to handle a number of different reagents and perform a number of different procedures on different samples automatically in an efficient, error-free manner. To facilitate the handling of different procedures, the Paramax system uses bar codes on the sample holders (test tubes). The Paramax system automatically reads the bar codes and supplies them to a microprocessor, which correlates the information with the test intended for the specimen, indicating the reagents to be dispensed in the process of analyzing the sample. (Liston '159, 6:30-36). The Driscoll reference states, "Identification of samples by affixing unique bar codes, printed by the analyzer upon test selection, enables error-free sample handling and random entry into the loading carousel, and facilitates 'stat' analysis." (Driscoll, p. 1615). The reagent dispensers are also coded so that the instrument can "identify the reagent contained in each dispenser" which "allows the loading of dispensers randomly." (Driscoll, p. 1609). The sample bar coding is useful for applying different tests to different samples. (Liston '159, 2:11-15, 4:34-37, 4:59-5:2).

14. This solution was known to pathologists, the customers of the machines of the '861 patent. In the U.S., pathologists are medical doctors (MD) or doctors of osteopathic medicine

(DO) that typically have completed a four year undergraduate program, four years of medical school, and four to five years of postgraduate training in the form of a pathology residency. While the American Board of Pathology has two primary certifications – Anatomic Pathology (AP), the science of diagnosing diseases based on the morphologic appearance of tissues (histopathology) and cell preparations (cytopathology), and Clinical Pathology (CP), the science of diagnosing diseases based on the analysis of bodily fluids – most pathologists (around 80%) seek training and certification in both AP and CP. A majority of pathologists concentrate on one or two subspecialties, which may be in one or both of AP and/or CP. Indeed, the subspecialty of hematopathology is an excellent example of a crossover subspecialty, where the practicing pathologist is called upon to concurrently exercise expertise in both AP and CP in the course of adjudicating over diagnostic material in the process of rendering diagnoses.

15. The clinical chemistry analyzer of Liston/Driscoll is an instrument for clinical pathology (CP). While immunostaining instruments are used in anatomic pathology (AP), the far majority of the pathologists that are the customers for AP instruments are certified in both AP and CP and are familiar with techniques from both CP and AP.

16. Historically the deployment of automation principles in CP has preceded their deployment in AP. This is not because of ignorance of these principles on the part of AP laboratorians or any perceived inapplicability of these principles to AP, but rather because the AP areas generally exhibited lower volumes of testing that typically did not warrant additional expenditure for automated solutions. Nevertheless, it was known within AP that automation facilitates highly individualized treatment and processing of specimens. For example, the Shoobridge reference (1983), describes an automated staining system. The system uses a

shorthand notation for stains that is "brief enough to write on a slide label and is convenient for manual or computer analysis." (Shoobridge, p. 249).

17. Articles such as Rappoport (1985) and Tilzer (1988) describe the utility of bar codes across a variety of health care sectors and "in all segments of the hospital, including the pharmacy, central service, radiology, and the medical laboratory." (Tilzer, p. 1200). A person of ordinary skill would have readily recognized that the bar coding techniques of Liston/Driscoll were applicable across both CP and AP.

C. Taking into account any such known solution(s), would the subject matter of the claims have been obvious to a person of ordinary skill in the art?

18. In my opinion, it would have been obvious to a person of ordinary skill designing an immunostaining instrument for automatically dispensing reagents onto slides to have applied the known solution of Liston/Driscoll. Specifically, in designing such an instrument, it would have been obvious, based on Liston/Driscoll, to (i) label the slides with bar codes that identify the samples and indicate (via a database) the reagents to be applied to the slide, and (ii) label the reagent containers with bar codes that identify the reagents in the reagent containers. Such an instrument meets each of the limitations of claims 1-3, 5, 6 and 8 of the '861 patent.

19. A person of ordinary skill would have recognized that bar coding as in Liston/Driscoll would be useful for an immunostaining instrument, providing the capability of automatically performing a number of different procedures and allowing random loading of reagents and samples. Thus, a person of ordinary skill would have found it obvious to employ the techniques from Liston/Driscoll in an immunostaining instrument.

20. I note that in Liston/Driscoll the samples are blood samples in test tubes (which carry the bar codes), and the blood samples are transferred from those test tubes to cuvettes which receive the reagents. A person of ordinary skill in the art designing an imunostaining instrument for the

application of reagents to slides would have known that the sample (e.g., tissue section) should remain on the slide and have reagents applied to it. A person of ordinary skill would have recognized that the bar codes on the test tubes of Liston/Driscoll would have utility in an automated slide staining machine, and would have found it obvious to apply such bar codes to the slides. It was well-known in the prior art to put bar codes on sample holders (e.g., slides, tubes, cuvettes) and on reagent containers for purposes of automation, resulting in efficiencies of speed, cost savings, and reducing errors. (*See*, *e.g.*, JP '957 (bar codes on slides, allowing random placement and reducing errors); Tilzer (bar codes on tubes, streamlining workflow and reducing potential errors); Keenan (bar codes on tubes, trays and slides, addressing issues of cost and enabling faster processing); JP '165 (bar codes on reagent containers, thereby prevent mistakes when reagents positions are entered using a keyboard or when reagents are put in the wrong position); Hauser '875 (bar codes on slides); Horne '299 (bar codes on slides); EASY Diagnostic (bar codes on cuvettes); Abbott SPECTRUM (bar codes on reagent containers); Parallel (bar codes on tubes); Sugaya '762 (bar codes on slides)).

21. In my opinion, the claims at issue (claims 1-3, 5, 6 and 8) are simply the use of bar coding as known from Liston/Driscoll in an instrument for dispensing reagents onto slides (as known, for example, from Stark and Cosgrove/Bowman). In that combination, the bar coding performs the same functions as it did in Liston/Driscoll. The claimed combination does not yield any results other than what would have been expected.

22. I understand that in analyzing obviousness, I should take into account objective considerations, such as whether the invention achieved "commercial success" due to the claimed features or met a "long-felt need." In the Second Hicks Report, Dr. Hicks raises "commercial success," asserting that "Ventana's automated slide staining systems have met with great success

and popularity." (Second Hicks Report, ¶ 10). However, Ventana experienced operating losses through at least 1996. (VEN 1036972). Ventana's sales (which were largely later) have been primarily attributable to the development of the market over time due to the increasing use of immunostaining procedures and not due to the features of the claims at issue. (VEN 1036968). Recent market information supports my conclusion. Vision's current Bond instruments have been commercially successful. (*See, e.g.*, VBS-OCR 0167955). This commercial success has been due to the Bond instruments' integration of processing steps and superior staining results, not because of bar coded slides (the current Bond does not even use bar coded slides but instead uses slides with optical character recognition (OCR) labels). This provides evidence that the commercial success of automated immunostaining instruments is not driven by the use of bar coding on slides. Ventana's relative success as compared to other companies has not been attributable to bar coding but instead has been primarily due to its instruments' control over the dispensing and processing steps to yield useful and consistent staining results. Antigen/epitope retrieval techniques have also contributed significantly. Dr. Hicks also raises "long-felt need," asserting that there was a "great need" for "years before the '861 patent" for a device having features as claimed. (Second Hicks Report, ¶ 9). However, as referenced above, it was only in 1985 that the AMA created the pertinent CPT code, in late 1989 efforts were still being made to develop quality control procedures, and as late as 1993 issues such as the reporting of immunostaining results were being addressed. In the late 1980's, the need was not long-felt.

III. U.S. Patent No. 5,122,432 to McCulloch

23. It is also my opinion that the invention claimed in claims 1-3, 5, 6 and 8 also would have been obvious in view of U.S. Patent No. 5,122,432 to McCulloch ("McCulloch"). Similar to Liston/Driscoll, McCulloch shows the known solution to the problem of handling a number of

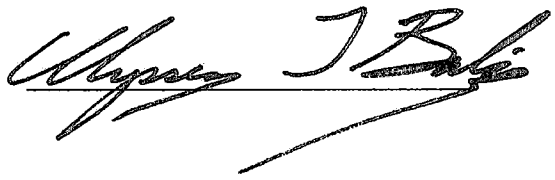
different reagents and performing different procedures on different samples in an efficient and error-free manner. McCulloch describes a bio-fluid assay apparatus useful for carrying out immuno-assay tests (like ELISA). The tests are carried out in microtitre plates carried by plate carriers, each of which has "a uniquely identifying machine readable label 28 which by reference to the data held by the micro-processor M will indicate the particular type of assay which the plate carried thereby is to undergo." (McCulloch, 3:1-5, 1:36-41). The machine also has "a machine readable label associated with each reagent dispenser and indicating the identity of the reagents carried thereby." (McCulloch, 1:66-2:1, 3:26-30). The codes on the plate carriers and reagent dispensers may be bar codes. (McCulloch, 4:9-10). The only difference between McCulloch and the claimed invention is that the bar codes in McCulloch are on microtitre plate carriers instead of slides. In my opinion, it would have been obvious to employ the automation advantages of McCulloch in an instrument for dispensing reagents onto slides, applying bar codes (as on the carrier plates of McCulloch) to the slides, and applying bar codes (as on the reagent dispensers of McCulloch) to the reagent containers. This obvious modification results in an instrument having all of the features in claims 1-3, 5, 6 and 8, rendering these claims obvious. I understand that because McCulloch was granted after (although filed before) the '861 patent, Ventana asserts that McCulloch does not qualify as prior art because Ventana allegedly made the invention before McCulloch's filing date. However, I understand that the independent making of the claimed invention by another at about the same time can be evidence of obviousness. McCulloch's independent design – of a machine that differs from the claimed invention only because the bar codes in McCulloch are on microtitre plate carriers instead of slides – is further evidence of the obviousness of the claims.

IV. Compensation and Testimony in Other Cases

24. I receive $200 per hour for time spent on this matter. My compensation is not dependent on the outcome of the case. I have not testified in any other cases in the past four years.

25. I may supplement this report if I become aware of additional pertinent information or in response to the testimony of others. Moreover, I may comment on, or testify in response to, the testimony of other witnesses, including witnesses who testify on behalf of Ventana.

Dated: 5/7/07



Tab A

CURRICULUM VITAE

Name: Ulysses Gregory John Balis
Email: ul@balis.com

Education:

9/1984 - 5/1987	Duke University, Durham, NC. B.S., (Computer Engineering – dual-major program)
9/1984 - 5/1987	Duke University, Durham, NC, B.S., (Biology – dual-major program)
8/1987 - 5/1991	University of South Florida, Tampa, FL, M.D.

Postdoctoral Training:

7/1991 - 6/1996	Residency in Combined Anatomic / Clinical Pathology University of Utah, Salt Lake City, UT
7/1996 - 6/1998	Postdoctoral Research Fellow Whitaker Foundation B.E.R.E. Program The Center for Engineering in Medicine, Massachusetts General Hospital and Harvard University Health Sciences and Technology Program
7/1998 - 6/2000	Research Associate Shriners Burns Hospital, Boston Unit and The Center for Engineering in Medicine, Massachusetts General Hospital
7/1996 - 6/2000	Research Fellow in Surgery (Bioengineering), Harvard University
7/1996 – 6/2000	Research Fellow in Surgery (Bioengineering), Massachusetts General Hospital

Licensure and Certification:

1991	National Board of Medical Examiners
1991- 1996	Physician, State of Utah
2000	Physician, Commonwealth of Massachusetts

Academic Appointments:

7/2000 – 6/2002	Instructor in Pathology, Harvard University
9/2002 - present	Assistant Professor of Pathology and Computer Engineering; Harvard Medical School

Academic Administrative Appointments

7/2000 -	Chief of Pathology and Laboratory Services, Shriners Hospital for Children, Boston Burns Unit
1/2002-	Director of Pathology Informatics, Massachusetts General Hospital
1/2004 – 4/2005	Acting Chief Information Officer, Shiners Hospital for Children, Boston Burns Unit
7/2000-	Directory of Laboratory Services, Shriners Hospitals for Children - Boston Burns Unit.

Hospital and Affiliated Institution Appointments

6/1992 - 6/1996	Founding Medical Director Core Instrumentation and Image Processing Laboratory Associated Regional and University Pathologists, Inc., Salt Lake City, Utah
7/1993 - 6/1996	Assistant Medical Director Flow Cytometry Clinical Laboratory. Associated Regional and University Pathologists, Inc., Salt Lake City, Utah
7/2000 -	Assistant in Pathology and Computer Science, Massachusetts General Hospital

Scientific Activities

1998 - 2000	Voting Member, Synoptic Nomenclature of Medicine (SNOMED) Editorial Board, College of American Pathologists
1999 -	Ad hoc reviewer; topics in telemedicine, tissue engineering. Journal of the American Medical Association
2000 -	Ad hoc reviewer; topics in quantitative PCR, Journal of Clinical Chemistry

2000 - 2003	Committee Advisor, Synoptic Nomenclature of Medicine (SNOMED) Editorial Board, College of American Pathologist
2003 -	Reviewer, Bioinformatics section, BioMed Central online publications

Grant Support

1990-1991	Intramural Departmental Grant, University of South Florida Department of Pathology. PI. *Wide Area Network (WAN) Telepathology Linkage of the James A. Haley Veterans Hospital and the Bay Pines Veterans Hospital*. $16,000.
1992-1996	Intramural Departmental Grant, University of Utah Department of Pathology / Associated Regional and University Pathologists, Inc. Founding Clinical Medical Director, *Core Instrumentation and Image Processing Laboratory*, $348,000.
2001-2006	Investigator, Shared Pathology Information Network (SPIN), National Cancer Institute (1U01CA091429-01); 20% Effort. P.I.: Zak Keohane, MD, PhD. $6,140,210 (5 years).
2000-	Principle Investigator, Danafarber Harvard Cancer Center (DFHCC) Virtual Specimen Locator Initiative (Intramural). 15% effort (5 years).
2005-	Investigator, A Novel Breast Cancer Biomarker. National Cancer Institute (1R01CA112021-01); 5 % effort. P.I.: Dennis Sgroi, M.D.
2005-	Investigator, Living Cell Arrays for Real Time Functional Genomics , National Institute Of Allergy And Infectious Diseases (1R01AI063795-01) 10 % effort. P.I.: Martin L. Yarmush, M.D., Ph.D.
2006-	Consultant: Inflammation and the Host Response to Injury (5U54GM062119-05) 10% effort. P.I. Ronald Tompkins, M.D., Sc.D.

Military Service

None

Honors and Awards

1982	Early Acceptance Honors Program Recipient, University of South Florida
1982	State of Florida Governor's Award of Distinction for Outstanding Academic Achievement
1984	Deans List, Duke University
1991	Annual Award for Excellence in Pathology and Laboratory Medicine, University of South Florida College of Medicine
1995	Presidential Service Award, College of American Pathologists

1996	Whitaker Foundation Bioengineering Fellowship Recipient Massachusetts General Hospital and Harvard Medical School
2000	Lansky Award, College of American Pathologists
2003	Society for Ultrastructural Pathology, Award for best ultrastructural abstract, United States and Canadian Academy of Pathology Annual Meeting.
2003	Best Scientific Session: for *Controlled Vocabularies, Decision Support and Outcome Research*, APIII Annual Meeting (Advancing Practice, Instruction and Innovation Through Informatics (Pittsburgh, October 6-8)
2003	Invited Keynote Speaker, Healthcare Informatics Society of Australia, Pathology Information Technology World Symposium. Gold Coast, Australia, September.
2005	Invited Visiting Fellow and Keynote Speaker, Australian Royal College of Pathologists; Pathology Update Meeting.
2005	Invited Visiting Fellow and Keynote Speaker Current Update in Telepthology, Provincial Laboratory Coordinating Office (PLCO); British Colombia, Canada.

Memberships in Professional Societies

1991-	College of American Pathologists, Committee Chair and Council Member
1992	World Congress of Non-linear Analysts, Member
1994-	Institute of Electrical and Electronic Engineers (IEEE), Member
1998-	IEEE Computer Society, Member
1998-	American Foundation for Greek Language and Culture (www.afglc.org)
2000-	Association of Pathology Informatics, Founding Member
2000-	American Medical Association, Member
2000 - 2006	Massachusetts Medical Society, Member

Teaching Activities

2000-	Massachusetts General Hospital Department of Pathology: Ongoing development and Extension of a Pathology Informatics Curriculum for the Residency Program
2000-	Massachusetts General Hospital Department of Pathology: Resident teaching of gastrointestinal surgical pathology.
2001-2006	Core Faculty: Massachusetts Institute of Technology - Harvard HST Program: *HST505: Laboratory in Molecular and Cellular Sciences* -- Advanced tutorials in scientific image acquisition and analysis; annual workshop/symposium.

Extramural Invited Presentations

Invited Lecture. Distributed Imaging with a Digitizing Videodisk Fileserver. Slice of Life V Workshops, Salt Lake City, Utah, 1992

Invited Lecture. Identification and Quantification of Attractor Metamorphosis in Digitized Histopathologic Images. Plenary Section: "Asymptotic Behavior of Nonlinear Systems: Attractors and Confinors: Application to Biology." First World Congress of Nonlinear Analysts, Tampa, Florida, 1992

Invited Lecture. Digital Image Resolution and Diagnostic Accuracy in Hematopathology. Spring ASCP/CAP National Meeting, 1993

Roundtable Seminar. The Digital Pathology Workstation, Spring ASCP/CAP National Meeting, 1993

Invited Lecture. Telepathology and Image Transfer. Fall ASCP/CAP National Meeting, 1993

Roundtable Seminar . The Digital Pathology Workstation. Fall ASCP/CAP National Meeting, 1993

Seminar, twice presented. Image Processing and Analysis for the Surgical Pathologist. Moderator and Presenter. Spring and Fall ASCP/CAP National Meetings, 1994

Invited Workshop. The Pathologist's Workstation. Fall ASCP/CAP National Meeting, 1994

Seminar, twice presented: Image Processing for the Pathologist. Moderator and Presenter. Spring and Fall ASCP/CAP National Meetings, 1995

Invited Lecture. DICOM and Pathology. Fall ASCP/CAP National Meeting, 1995

Roundtable Seminar. The Digital Pathology Workstation. Fall ASCP/CAP National Meeting, 1995

Invited Demonstration. Pathologists in the Cockpit; Demonstration of Real-time robotics telepathology at the Department of Pathology, University of Utah. *Infofair '96 - Becoming Digital*. Spencer S. Eccles Health Sciences Library, Salt Lake City, 1996

Seminar. Advanced Tutorials in Image Processing and Analysis for Pathology. Spring ASCP/CAP National Meeting, 1996

Invited Lecture. Global World Wide Web for Pathologists. Fall ASCP/CAP National Meeting, 1996

Invited Lecture. Implementation Issues in Telepathology. University of South Florida Department of Pathology Grand Rounds, 1997

Workshop Seminar. Telepathology and Standards for Enhanced Productivity. Spring ASCP/CAP National Meeting, 1997

Seminar. Global World Wide Web. Spring ASCP/CAP National Meeting, 1997

Roundtable Seminar. Desktop Imaging for the Pathologist. Fall ASCP/CAP National Meeting, 1997

Invited Seminar. Digital Pathology. Fall ASCP/CAP National Meeting, 1997

Invited Roundtable Seminar. Desktop Imaging for the Pathologist. Spring ASCP/CAP National Meeting, 1998

Invited Lecture. The Internet Demystified: Technical Aspects of TCP/IP and HTML Interoperability. Spring ASCP/CAP National Meeting, 1998

Invited Seminar & Workshop. Telefest! State of the art issues in telepathology with demonstrations. Spring ASCP/CAP National Meeting, 1998

Invited Lecture. Informatics Weekend Resident Symposium. Fall ASCP/CAP National Meeting, 1998

Invited Lecture. Automated Synoptic Reporting. Fall ASCP/CAP National Meeting, 1998

Invited Lecture. Biotech and Infotech Opportunities for Pathologists. Fall ASCP/CAP National Meeting, 1998

Seminar. Laboratory Statistics You Will Actually Use. Fall ASCP/CAP National Meeting, 1998

Roundtable Seminar. Desktop Imaging for the Pathologist. Fall ASCP/CAP National Meeting, 1998

Invited Lecture. Telepathology Update. Pathology Grand Rounds. University of South Florida Health Sciences Center, Tampa, FL, 1998

Invited Lecture. Bioartificial Liver Technology in Review. Pathology Lecture Series. University of South Florida Health Sciences Center, Tampa, FL., 1999

Roundtable Seminar. Desktop Imaging for the Pathologist. Spring ASCP/CAP National Meeting, 1999

Invited Teleconference Seminar. A Primer on Digital Imaging. American Society of Cytopathology Teleconference, May 25, 1999

Roundtable Seminar. PERL programming for the Pathologist. Fall ASCP/CAP National Meeting, 1999

Roundtable Seminar. Desktop Imaging for the Pathologist. Spring ASCP/CAP National Meeting, 2000

Invited Lecture. State of the Art Digital Pathology, Southwest Florida Association of Pathology Grand Rounds Series, Sarasota, FL., June, 2000.

Roundtable Seminar: Desktop Imaging for the Pathologist. Fall ASCP/CAP National Meeting, 2000

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences*. Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2000 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Pathology Grand Rounds: Current A review of Clinical State of the Art in Bioartificial Liver Support Systems. Scripps Medical Center, April, La Jolla, CA, 2001

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences*. Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2001 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Lecture, Images Are Not Enough: Integration of Data and Images In a Fully Integrated Electronic Medical Record System, University of Minnesota, Minneapolis, MN., June, 2001

Synthetic Microscopy for True Digital Signout: Roundtable Session. ASCP/CAP National Meeting, Philadelphia, PA, October, 2001

Web-Based Digital Microscopy. ASCP/CAP National Meeting, Philadelphia, PA, October, 2001.

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences*. Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2002 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Lecture: Cognitive learning and educational digital imaging repositories. Group for Research in Pathology Education (GRIPE) Annual Meeting; University of South Florida, Tampa FL, January, 2002.

Invited Lecture, Standardization of Interoperable Pathology Reporting. APIII Annual Meeting. Pittsburgh, PA, October, 2002.

Invited Focus Group Participant: Tissue Microarray Application Data Exchange Standards. APIII Annual Meeting. Pittsburgh, PA, October, 2002.

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences*. Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2003 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Keynote Speaker, Healthcare Informatics Society of Australia, Pathology Information Technology World Symposium. Gold Coast, Australia, September, 2003.

Invited Scientific Presentation: Automated Deidentification of Pathology Reports, Beckwith B, Kuo F, Balis UJ. APIII Annual Meeting. Pittsburgh, PA, October, 2003.

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences*. Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2004 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Scientific Presentation: Implementation of a Region of Interest-Based Query Using Vector Quantization, Generalized Affine Class-based Vocabularies and Multimodal Chebyshev Polynomial Normalization to Retrieve Context-matched Imagery from Existing Digital Image Repositories, , Balis UJ. APIII Annual Meeting, Pittsburgh, PA, October, 2004.

Invited Presentation: Current Developments in Imaging and Informatics for the Practicing Surgical Pathologist. Harvard Medical School Current Concepts in Surgical Pathology. November 2004.

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences.* Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2005 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Scientific Presentation: Region-of-Interest Based Differential Diagnosis Via the Use of Vector Quantization and N-Dimensional Bayesian Voronoi Mapping. Balis UJ. APIII Annual Meeting. Pittsburgh, PA, October. Lake Tahoe, NV, August 2005.

Invited Presentation: Current Developments in Imaging and Informatics for the Practicing Surgical Pathologist. Harvard Medical School Current Concepts in Surgical Pathology. November 2005.

Invited Keynote Speaker: Provincial Laboratory Coordinating Office of British Columbia Telepathology Symposium. "Telepathology: From Theory To Implementation." Vancouver, BC, December 7, 2005. http://www.plco.ca/news5.html

Annual Course on Advanced Tutorials in Biological Image Analysis and Image Processing. HST505: *Laboratory in Molecular and Cellular Sciences.* Massachusetts Institute of Technology HST Seminar Graduate Program, Cambridge, MA., January, 2006 See: http://hst.mit.edu/servlet/ControllerServlet?handler=PublicHandler&action=viewCourse&courseID=HST+505&term=2003JA

Invited Presentation: Lab Infotech Summit. "Searching Surgical Pathology Databases with Images Instead of Words." Las Vegas, NV, March 2, 2006. https://www.labinfotech.org/LIS2006/Conference_Agenda.php

Committee and Administrative Service

Institutional

2000 -	Co-director, MGH Division of Anatomic Pathology Website Development taskforce
2001-2002	Member, MGH Division of Anatomic Pathology AP Information System Search Committee.
2002-	Joint MGH/BWH Anatomic Pathology Implementation Task Force, Partners Healthcare Information Systems Division
2002-	Team Pathologist, MGH Division of Anatomic Pathology AP Information System Implementation Project (tandem project with Brigham and Woman's Hospital AP Information System Implementation)
2003-	Information System (SHCIS) Implementation; Acting CIO, Shriners Hospital for Children – Boston Burns Unit
2003-	Member, Standing Readiness Task force for Joint Commission Surveys, Shriners Hospital for Children, Boston Burns Unit

National and International

1992-1995	Member, Informatics Committee, College of American Pathologists
1993-1994	Liaison to ANSI/HISB (American National Standards Institute / Healthcare Information Standards Board),College of American Pathologists
1993-1994	Member, Cytology Proficiency Testing Advanced Technology Ad Hoc Search Committee,College of American Pathologists
1993-1996	Liaison to ACR/NEMA (American College of Radiology / National Electrical Manufacturers Association), College of American Pathologists
1994-1996	Member, University of Utah Health Sciences Center Telemedicine Outreach Committee
1994-1996	Founding Chair, Image Exchange Committee, College of American Pathologists
1994-1996	Adjunct Member, Council on Practice Management College of American Pathologists
1995-1996	Founding Member, World Wide Web Task Force, College of American Pathologists
1995	Member, Informatics Subcommittee for Revising the Information Systems Section of the Laboratory Inspection Checklist, College of American Pathologists
1996-1998	Liaison to ANSI/HISB (American National Standards Institute / Healthcare Information Standards Board), College of American Pathologists
1997-1998	Member, Informatics Committee,College of American Pathologists
1997-1998	Member, Informatics Subcommittee for Revising the Information Systems Section of the Laboratory Inspection Checklist, College of American Pathologists
1997-2004	Principle Voting Delegate to DICOM, College of American Pathologists
1998-2000	Member, SNOMED Editorial Board, College of American Pathologists
1999-2002	Chair, Informatics Committee,College of American Pathologists
1999-2001	Member, Council on Practice and Education (COPE),College of American Pathologists
2000-2001	Member, Education Cluster Committee of the Council on Practice and Education (COPE), College of American Pathologists
2000-	National Institutes of Health *Center for Scientific Review* Site Visit Study Section, National Supercomputing Centers Special Opportunity Funding for Pathology Informatics

2001-2003	Advisor, SNOMED Editorial Board
2001-2004	CAP Delegate to DICOM Structured Reporting Working Group
2001-	Laboratory and Diagnostic Anatomic Pathology Image Exchange Standards Task Force - Association of Pathology Informatics
2001-2002	Member, Information Sciences Council, College of American Pathologists
2003-2004	Advisor, Informatics Committee, College of American Pathologists
2002-2004	Training and Education and Education Committee Chair, Association for Pathology Informatics
2005-2006	Vice President, Association for Pathology Informatics
2006-2007	President-Elect, Association for Pathology Informatics

Community Service

2001-	Senior Managing Editor and Chief Information Officer, American Foundation for GreekLanguage and Culture (www.afglc.org)

Patents

6,759,245. CELL CULTURE SYSTEMS AND METHODS FOR ORGAN ASSIST DEVICES. **Toner; Mehmet** (Wellesley, MA); **Tilles; Arno W.** (Cambridge, MA); **Balis; Ulysses J.** (Peabody, MA); **Yarmush; Martin L.** (Newton, MA); **Cosman; Maury D.** (Woburn, MA); **Dimilla; Paul A.** (Dover, MA)

6,562,616 Methods and devices for cell culturing and organ assist systems. **Toner; Mehmet** (Wellesley, MA); **Yarmush; Martin L.** (Newton, MA); **Balis; Ulysses J.** (Peabody, MA); **Tilles; Arno W.** (Cambridge, MA)

Technology Transfer

Automated Barcode tracking system for Anatomic Pathology Workflow. Licensed to Impac Medical Systems by MGH Corporate Sponsored Licensing and Research, 2005. Royalty terms: $250,000.

Bibliography:

Peer-reviewed publications:

1. Balis UJ, Aller RD, Ashwood ER. Informatics Training in U.S. Pathology Residency Programs: Results of a Survey. Pathol Patterns 1993;100:44-47.

2. Balis UJ, Morris KF, Koleski J, Lindsey BG. Simulations of a ventrolateral medullary neural network for respiratory rhythmogenesis inferred from spike train cross-correlation. Biol. Cybern. 1994;70:311-327.

3. O'Donnell LR, Alder SL, Balis UJ, Perkins SL, and Kjeldsberg CR. Immunohistochemical Reference Ranges for B-Lymphocytes in Bone Marrow Biopsy Paraffin Sections. Am J Clin Pathol 1995;104:517-523.

4. Wittwer CT, Ririe KM, Andrew RV, David DA, Gundry RA and Balis UJ. The LightCyclerTM: A Microvolume Multisample Fluorimeter with Rapid Temperature Control. Biotechniques 1997;22:176-179.

5. Balis UJ Digital imaging standards and system interoperability. Clin Lab Med. 1997;17:315-322.

6. Balis UJ Telemedicine and telepathology. Clin Lab Med. 1997;17:245-261.

7. Balis UJ Optical considerations in digital imaging. Clin Lab Med. 1997;17:189-200.

8. Balis UJ Image output technology. Clin Lab Med. 1997;17:175-188.

9. Balis UJ Imaging input technology. Clin Lab Med. 1997;17:151-174.

10. Bhatia SN, Balis UJ, Yarmush ML, Toner M Microfabrication of hepatocyte/fibroblast co-cultures: role of homotypic cell interactions. Biotechnol Prog 1998;14:378-387.

11. Bhatia SN, Balis UJ, Yarmush ML, Toner M, Probing heterotypic cell interactions: hepatocyte function in microfabricated co-cultures. J Biomater Sci 1998;9(Polymer Edition):1137-60.

12. Shito M, Balis UJ, Thompkins RG, Yarmush ML, Toner M. Survival and blood chemistry of fulminant hepatic failure model in the rat: involvement of interleukin-1 beta and tumor necrosis factor-alpha. Gastroenterology 1999;116(part 2):A646-A646.

13. Balis UJ. Alternative careers in the laboratory re-engineering paradigm. Clin Lab Med. 1999;19:453-61.

14. Balis UJ, Behnia K, Dwarakanath B, Bhatia SN, Sullivan S, Yarmush ML and Toner M, Oxygen Consumption Characteristics of Porcine Hepatocytes. Metabolic Engineering 1999;1:49-62.

15. Ledezma GA, Folch A, Bhatia SN, Balis UJ, Yarmush ML, Toner M, Numerical model of fluid flow and oxygen transport in a radial-flow microchannel containing hepatocytes. J Biomech Eng 1999;121:58-64.

16. Bhatia SN, Balis UJ, Yarmush ML, et al. Effect of cell-cell interactions in preservation of cellular phenotype: cocultivation of hepatocytes and nonparenchymal cells. FASEB J 1999;13:1883-1900.

17. Behnia K, Bhatia S, Jastromb N, Balis UJ, Sullivan S, Yarmush ML, Toner M. Xenobiotic metabolism by cultured primary porcine hepatocytes. Tissue Engineering 2000; 6 (5): 467-479.

18. Balis UJ, Tilles AW, Baskaran H, Yarmush ML, Toner M. Internal Membrane Oxygenation Removes Substrate Oxygen Limitations in a Small-Scale Hepatocyte Bioreactor. Tissue Engineering for Therapeutic Use 5, Ikada, Y. and Ohshima, N. (editors), 2001.

19. Shito M, Balis UJ, Tompkins RG, Yarmush ML, Toner M. A Fulminant Hepatic Failure Model in the Rat. Involvement of Interleukin-1β and Tumor Necrosis Factor-α. Digest Dis Sci 2001;46 (8): 1700-1708.

20. Lauwers GY, Furman J, Michael LE, Balis UJ, Kubilis PS. Cytoskeletal & Kinetic Epithelial Differences Between NSAID Gastropathy and H. Pylori Gastritis: An Immunohistochemical Determination. Histopathology 2001;39 (2): 133-140.

21. Lauwers GY, Terris B, Balis UJ, Batts KP, Regimbeau JM, Chang Y, Graeme-Cook F, Yamabe H, Ikai I, Cleary KR, Fujita S, Flejou JF, Zukerberg LR, Nagorney DM, Belghiti J, Yamaoka Y, Vauthey JN; International Cooperative Study Group on Hepatocellular Carcinoma. Prognostic histologic indicators of curatively resected hepatocellular carcinomas: a multi-institutional analysis of 425 patients with definition of a histologic prognostic index. Am J Surg Pathol. 2002;26(1):25-34.

22. Balis UJ, Yarmush ML and Toner M. Bio-Artificial Liver Process Monitoring and Control Systems With Integrated Systems Capability. Tissue Engineering 2002;8(3): 483-498.

23. Schaefer PW, Lucey BC, King ME, Samuels MA, Colvin RB, Singhal AB, Balis U. A 61-year-old man with headache and multiple infarcts. Adenocarcinoma, probably of pancreaticobiliary origin and metastatic to the liver, with a hypercoagulable state resulting in thrombophlebitis and nonbacterial thrombotic endocarditis, with multiple embolic infarcts (Trousseau's syndrome). New Eng J. Med 2002;347(15): 1187-1194.

24. Misdraji J, Yantiss RK, Graeme-Cook FM, Balis UJ, Young RH. Appendiceal mucinous neoplasms: a clinicopathologic analysis of 107 cases. Am J Surg Pathol. 2003 ;27(8):1089-103.

25. Ross AM, Anupindi SA, Kleinman RE, Ryan DP, Balis UJ. A 14-year-old boy with ulcerative colitis, primary sclerosing cholangitis, and partial duodenal obstruction - Cholangiocarcinoma, with duodenal stricture New Eng J. Med 2003;348(15): 1464-1476.

26. Mokuno Y, Berthiaume F, Tompkins RG, Balis UJ, Yarmush ML. Technique for expanding the donor liver pool: Heat shock preconditioning in a rat fatty liver model. Liver Transpl. 2004;10(2):264-72.

27. Ma XJ, Wang Z, Ryan PD, Isakoff SJ, Barmettler A, Fuller A, Muir B, Mohapatra G, Salunga R, Tuggle JT, Tran Y, Tran D, Tassin A, Amon P, Wang W, Wang W, Enright E, Stecker K, Estepa-Sabal E, Smith B, Younger J, Balis U, Michaelson J, Bhan A, Habin K, Baer TM, Brugge J, Haber DA, Erlander MG, Sgroi DC. A two-gene expression ratio predicts clinical outcome in breast cancer patients treated with tamoxifen. Cancer Cell. 2004 Jun;5(6):607-16.

28. Beckwith BA, Mahaadevan R, Balis UJ, Kuo F. Development and evaluation of an open source software tool for deidentification of pathology reports. BMC Med Inform Decis Mak. 2006 Mar 6;6:12.

Reviews, Chapters and Editorials

1. Aller, RD and Balis, UJ. Informatics, Imaging and the Pathologist's Workstation. In: Henry JB, MD, editor. Clinical Diagnosis and Management by Laboratory Methods, (19th Edition), Philadelphia: W. B. Saunders; 1996. p. 92-124.

2. Balis UJ, editor. Imaging in the Clinical Laboratory. In: Pathology Clinics of North America. Philadelphia: W.B. Saunders; 1997.

3. Aller, RD and Balis, UJ. Informatics, Imaging and Interoperability. In: Henry JB, MD, editor. Clinical Diagnosis and Management by Laboratory Methods, (20th Edition), Philadelphia: W. B. Saunders; 2001.

4. Balis UJ and Lauwers GY, Pathology and Natural History of Hepatocellular Carcinoma. In: Abruzzese JL, Editor. Principles and Practice of Gastrointestinal Oncology, Oxford University Press, October, 2003.

Books

Houser S, Balis, UJ, Mark EJ. Lung Pathology: A Consultative Atlas. In: Humana Press, August 2005. *(hardcover and CD-ROM versions)*

International Standards

Balis UJ, CAP delegate, Bidgood WD, ACR delegate, Korman L, ASGE Delegate, Hildebrand L., AAO Delegate, editors. Supplement 15 for Digital Imaging and Communications in Medicine 3.0 (DICOM); Visible Light Image for Endoscopy, Microscopy, and Photography. Ratified June 9, 1999.

Scientific Advisory Boards,

1. Aperio Technology, Vista. CA
   http://www.aperio.com/company/Aperio-bd-of-directors.asp
2. Impac Medical Systems, San Jose, CA
   http://www.impac.com/company/pressroom/ind_prs/ipr58050503.html
3. Living Microsystems, Inc., Watertown MA
   http://www.livingmicrosystems.com/ourTeam.html
4. Cellpoint Diagnostics, Inc. Watertown MA

Clinical Communications

1. Weilert M, Balis UJ, Aller RD, Carey K. AP system imaging capability: an emerging technology. CAP Today, p.37, 1993.

2. Skjei, E. Bringing order to data chaos. *(Telephone interview contents quoted within article). CAP Today* November 2003.

Selected Abstracts

1. Arnell PM, Selig MK, Nielsen GP, Balis UJ, Computer assisted three-dimensional reconstruction and visualization of the Birbeck granule. Lab Invest 2003;83(1): 1506.

2. Flotte TJ, Saleemuddin A, Balis U, Wide-field digital microscopy produces diagnostic quality images for telepathology. Modern Pathol 2003;16(1): 1469.

TAB B – MATERIALS REVIEWED

Materials Identified in the First Hicks Report (First Hicks Report, ¶ 6)

Document	Bates Number
Expert Report of Doug Koebler Regarding U.S. Patent No. 6,352,861 ("Koebler 1"), and the materials attached to that report	
U.S. Patent No. 6,352,861 to Copeland et al. ("the '861 patent")	VBS 13910-13962
Prosecution History of the '861 Patent	VBS 13963-14192
Stark et al., *An automated device for immunocytochemistry*, J. of Immunological Methods, vol. 107, pp. 89-92 (1988) ("Stark")	VEN 002316-002319
Keenan et al., *Patient Identification in an Automated Clinical Laboratory System*, IEEE Frontiers of Eng. in Health Care, pp. 15-18 (1982) ("Keenan")	VBS-OCR 0164093-0164096
Tilzer et al., *Use of Bar Code Labels on Collection Tubes for Specimen Management in the Clinical Laboratory*, Arch. Pathol. Lab. Med., vol. 112, pp. 1200-1202 (Dec. 1988) ("Tilzer")	VEN 015301-015308
U.S. Patent No. 4,159,875 to Hauser ("Hauser")	VBS-OCR 0164609-0164613
English translation of Kojima et al., Analyzing Method of Blood Image, Japanese Pat. App. Pub. No. 55-107957 (1980) ("JP '957")	VEN 015301-015308
U.S. Patent No. 4,528,159 to Liston ("Liston '159")	VBS 03443-03452
Driscoll et al., *Discrete Automated Chemistry System with Tableted Reagents*, Clin. Chem., vol. 29, pp. 1609-1615 (1983) ("Driscoll")	VBS 03419-03425
English translation of Japanese Pat. App. Pub. No. 63-61165 (1988) ("JP '165")	VEN 015315-015320

TAB B – MATERIALS REVIEWED

Materials Identified in the Second Hicks Report (Second Hicks Report, ¶ 4)

Document	Bates Number
Supplemental Expert Report of Doug Koebler Regarding U.S. Patent No. 6,352,861 ("Koebler 2"), and materials identified in that report	
U.S. Patent No. 4,430,299 to Horne ("Horne '299")	VBS 14345-61
Rappoport, Arthur E., *If Bar Codes Work in Supermarkets, It Should Be Great for Medicine*, Pathologist, vol. 39, no. 2, pp. 39-40 (1985) ("Rappoport")	VEN 15346-47
Advertisement: *The Age of EASY Diagnostic Testing*, EM Diagnostic Systems, Inc., as published in Clinical Chemistry, vol. 31, no. 6 (1985) ("EASY Diagnostic")	VBS 14390-91, 14397
Advertisement: *Abbott Spectrum*, as published in Clinical Chemistry, vol. 3, no. 31 (1985) ("Abbott SPECTRUM")	VBS 14388, 14399
Advertisement: *Parallel Analytical System*, American Monitor Corporation, as published in Clinical Chemistry, vol. 31, no. 1, p. 20A (1985) ("Parallel")	VBS 14411-16
U.S. Patent No. 4,800,762 to Sugaya ("Sugaya '762")	VBS 14411-16
Court Memorandum and Order dated September 30, 2004	

TAB B – MATERIALS REVIEWED

Materials Cited or Discussed in the '861 Patent

Document	Bates Number
Stross, W.P. et al., *Automation of APAAP immunocytochemical technique*, J. Clin. Pathol., vol. 42, pp. 106-112 (1989) ("Stross")	VBS-OCR 0168013-0168019
Cosgrove, R.F., *Design and application of an instrument for automated immunostaining*, Am. Clinical Laboratory, vol. 8, no. 12, pp. 23-27 (1989) ("Cosgrove")	VBS-OCR 0164078-0164082
Brigati, David J. et al., *Immunocytochemistry is Automated: Development of a Robotic Workstation Based Upon the Capillary Action Principle*, J. Histotechnology, vol. 11, no. 3, pp. 165-183 (1988) ("Brigati")	VEN 003329-003347
U.S. Patent No. 4,985,206 to Bowman ("Bowman")	VEN 28952-28960

Materials from Vision's Notice Under 35 U.S.C. § 282, June 27, 2005 (D.I. 118)

Document	Bates Number
Shi et al., *Antigen Retrieval Immunohistocemistry: Past, Present, and Future*, The Journal of Histochemistry and Cytochemistry, vol. 45(3), pp. 327-343 (1997) ("Shi 1")	Exhibit 18 of May 9, 2005 Deposition of D. Hicks (D.Mass. 03-cv-10391)
Shi et al., *Standardization of Immunohistochemistry Based on Antigen Retrieval Technique for Routine Formalin-fixed Tissue Sections*, Applied Immunohistochemistry, vol. 6(2), pp. 89-96 (1998) ("Shi 2")	Exhibit 17 of May 9, 2005 Deposition of D. Hicks (D.Mass. 03-cv-10391)

TAB B – MATERIALS REVIEWED

Additional Materials Reviewed

Document	Bates Number
KSR International Co. v. Teleflex, Inc., 04-350 (U.S. Supreme Court, April 30, 2007)	
Fed. Cir. Bar Model Patent Jury Instructions (excerpts)	VBS-OCR 0168002-0168012
AIPLA's Model Patent Jury Instructions (excerpts)	VBS-OCR 0167956-0168002
Bond Revenue Generators Global graph	VBS-OCR 0167955
Report, *Ventana Medical Systems, Inc.*, Cleary Gull Reiland & McDevitt, Inc. (1997)	VEN 1036967-1036982
Shoobridge, Michael P.K., *A New Principle in Polychrome Staining: A System of Automated Staining, Complementary to Hematoxylin and Eosin, and Usable as a Research Tool*, Stain Technology, Vol. 58, No. 5, pp. 245-258 (1983) ("Shoobridge")	VBS-OCR 0164588-0164603
Clausser, S.B. et al., Physicians' Current Procedural Terminology, Fourth Edition, American Medical Association (1985) ("CPT 1985 Codebook")	VBS-OCR 0164097-0164587
Elias, J. M. et al., *Special Report: Quality Control in Immunohistochemistry*, Amer. J. Clin. Pathol. Vol. 92, No. 6, pp. 836-843 (1989) ("Elias")	VBS-OCR 0164083-0164092
Banks, P.M. et al., *Incorporation of Immunostaining Data in Anatomic Pathology Reports*, Amer. J. Clin. Pathol., Vol. 99, No. 1, p. 7 (1993) ("Banks")	VBS-OCR 164075-0164077
U.S. Patent No. 5,122,432 to McCulloch ("McCulloch")	VBS-OCR 0165290-0165295
The ABP Examiner, vol. 29, no. 1 (Jan. 2007)	VBS-OCR 168020-168022